

PSJ3

Exhibit 339B

Pursuant to the November 20, 2012 Prehearing Ruling, the Government hereby submits its Supplemental Prehearing Statement.

The Government supplements the proposed testimony of its previously disclosed witnesses as follows:

1. Deputy Assistant Administrator Joseph Rannazzisi

Both the ISO and the Government's Prehearing Statement refer to three letters issued by Deputy Administrator Rannazzissi. The second of these two letters, dated February 7, 2007, is identical to the first, dated September 27, 2006. The Government therefore will not be referencing the February 7, 2007 letter in its proposed testimony and has removed this document from its exhibit list.

Deputy Administrator Rannazzissi will further testify in response to Respondent's contention in its Prehearing Statement that its suspicious orders program was modeled on guidance from DEA's website. He will testify that Respondent's reliance on this website is misplaced, as it applies to DEA's Chemical Program only and is designed to implement separate statutes and regulations than those involving suspicious orders for controlled substances.

2. DPM Langston:

Ms. Langston will further testify to her review of the materials provided by Respondent in response to a subpoena request for the distributor's due diligence and customer files. Utilizing her training and experience in investigating manufacturers and distributors of controlled substances, she will testify that she found little to no evidence that Respondent or any part of its vertically integrated corporate structure undertook any efforts to assess the reasonableness or legitimacy of the orders it was shipping to Walgreens stores, despite the fact that it routinely identified these orders as suspicious. (To the extent this testimony is duplicative of that

proffered for A/GS Richards, Ms. Langston's testimony on these matters will be in place of Ms. Richards.) Correcting her proffered testimony in the government's Prehearing Statement, Ms. Langston will testify that the last suspicious control drug orders report received by DEA on behalf of Respondent was in February 2012, covering orders through January 2012.

3. Diversion Investigator ("DI") Phyllis Garrett:

DI Garrett (or, in the alternative, GS Richards) will additionally testify that Respondent's Suspicious Order Reports frequently failed to fully report all orders that, pursuant to their own criteria, should have been reported as suspicious. She will identify and describe a chart with supporting documentation, showing examples of these failures, some of which also include failures to report orders of Schedule II drugs to ARCOS. She will similarly identify and describe a summary of orders shipped by Respondent in early 2012, after it adopted a policy of no longer making suspicious order reports on the basis that it would not ship them, that exceeded its 2011 and January 2012 criteria for reporting those orders as suspicious.

DI Garrett (or, in the alternative GS Richards) will identify Walgreens "Oxycodone Action Plan" Memo for District 227 and compare the plan's intent to impose immediate order limits on three stores with the actual orders shipped by Respondent subsequent to this plan.

4. George Corripio

Pharmacist George Corripio will testify that he was temporarily transferred from Fort Pierce Walgreens 5079 to Walgreens Store # 4727, Fort Pierce, Florida, for a brief period in late 2010 (vice 2011 as stated in the Government's Prehearing Statement.) He will testify to the sharp contrast in clientele and dispensing practices between 4727 and 5079, despite their relative close proximity. He will testify that much of Store #4727's oxycodone customers appeared to be young, healthy individuals, whose appearance did not correspond with the medication they were

seeking or the diagnosis codes he obtained from the offices of the clinics issuing the prescriptions. Many times, the customers seeking the pain medications would arrive in groups who all seemed to know each other and they often appeared to be under the influence of something, which was suspicious to him based on his years of experience as a pharmacist. He will testify that the pharmacy supervisor, Andrea Cohen, told him that all he had to do to in order to fill a prescription was to get a diagnosis code from the issuing office. Because of his own discomfort in filling these prescriptions which he readily identified as suspicious, Andrea Cohen offered to fill them for him. He will testify that the offices whose customers presented pain prescriptions at 4727 generally provided the same diagnosis, usually low back pain, and that he observed that if 4727 filled one of these questionable prescriptions, they would soon see several more customers presenting similarly questionable prescriptions. He will testify that many times when he refused to fill these prescriptions, the customers would get angry and ask when the female pharmacist was coming back. He will testify that the majority of these customers paid cash and were encouraged to return to the pharmacy by Supervisor Andrea Cohen, who would offer these customers Walgreens discount cards. He will testify that he told law enforcement officers that the situation at 4727 with regards to the pill-seeking customers was out of control and that he needed help.

He will testify about an incident he reported to the police after he mistakenly provided extra oxycodone to customer Richard Hanson. Upon trying to call Hanson to tell him to return the oxycodone, Hanson's girlfriend told him that Hanson was an addict who sells his pills. He will be asked about whether there is anything in Walgreens dispensing system to note such an incident in order to flag a customer such as Hanson should he present prescriptions in the future for similar substances.

Proposed Exhibits:

Pursuant to the Court's Prehearing Ruling, the Government produced the following proposed exhibits to Respondent on November 30, 2012:

Exhibit	Description	# Pages
1.	DEA Certificate of Registration RW0277752	1
2.	September 27, 2006 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	8
3.	December 27, 2007 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	4
4.	April 2011 Memorandum of Agreement Between Walgreen Co. and DEA	7
5.	July 1, 2011 Florida State Department of Health Declaration of Public Health Emergency Regarding Prescription Drug Abuse Epidemic	5
6.	October 17, 2008 Healthcare Distribution Management Association Guidance with Attached Letter for DEA Chief Counsel Wendy Goggin	17
7.	February 15, 2005 Walgreens Policy: "Handling Suspicious Drug Orders"	2
8.	Notes on Walgreens Proposed Suspicious Order Policy	2
9.	April 4, 2012 Walgreens Policy: "Handling Suspicious Orders and Loss of Controlled Drugs"	1
10.	April 4, 2012 Walgreens Policy: "Handling Suspicious Drug Orders"	1
11.	Walgreens "Controlled Substance Threshold" Project P09002, February 2009	18
12.	December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	1626
13.	December 2011 Walgreens Jupiter Distribution Center C3-5 Suspicious Order Report	384

14.	Excerpt of December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	25
15.	Excerpt of August 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
16.	Excerpt of July 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
17.	Excerpt of June 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
18.	Excerpt of December 2010 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	36
19.	Excerpt of Suspicious Orders for Walgreens #3099	14
20.	Excerpt of Suspicious Orders for Walgreens #3629	64
21.	Excerpt of Suspicious Orders for Walgreens #3836	49
22.	Excerpt of Suspicious Orders for Walgreens #4391	34
23.	Excerpt of Suspicious Orders for Walgreens #4727	19
24.	Excerpt of Suspicious Orders for Walgreens #6997	15
25.	Walgreens Ft. Pierce Comparison of ARCOS Data and Chart	1
26.	Walgreens Oviedo Comparison of ARCOS Data and Chart	1
27.	Walgreens Port Richey and Hudson Comparison of ARCOS Data and Chart	1
28.	Walgreens Ft. Myers Comparison of ARCOS Data and Chart	1
29.	Top 100 Walgreens Purchasers of Oxycodone from Jupiter Distribution Center	3
30.	Yearly Sales of Oxycodone to Select Walgreens Pharmacies from All Sources, 209-2011	1
31.	Orders for 30mg Oxycodone (100 count bottles) in 2012 Exceeding Walgreens 2011 "Trigger Amount" for Reporting Suspicious Transactions, with Attached DEA Forms 222	23
32.	Walgreens Ft. Pierce (#4391) ARCOS Reporting Discrepancies	28
33.	Walgreens Ft. Pierce (#4727) ARCOS Reporting Discrepancies	21
34.	Walgreens Ft. Meyers (#3099) ARCOS Reporting Discrepancies	25
35.	Walgreens Hudson (#3629) ARCOS Reporting Discrepancies	41

36.	Walgreens Oviedo (#6997) ARCOS Reporting Discrepancies	22
37.	Walgreens Port Richey (#3836) ARCOS Reporting Discrepancies	30
38.	Suspicious Order Report Discrepancies	39
39.	DEA Guidance "A Pharmacist's Guide to Prescription Fraud"	2
40.	September 27, 2010 Ft. Pierce Police Incident Report for Richard Frederick Hanson	5
41.	Copies of Prescriptions Filled for Richard Frederick Hanson by Walgreens #4727	10
42.	November 4, 2011 Ft. Pierce Police Incident Report from Walgreens #4727	6
43.	Copies of Prescriptions Filled for Carlo Pastor by Walgreens #4727	18
44.	December 24, 2010 Police Incident Report Regarding James McCune and Accompanying Prescriptions	18
45.	Dispensing Log of Prescriptions Filled by Walgreens #3629 for James McCune	1
46.	Letters sent from Oviedo Police Department to Walgreens	16
47.	Summary of Arrests Made at Walgreens Pharmacies in Oviedo, Florida	1
48.	Summary of Surveillance Conducted at Walgreens Oviedo Pharmacies and Law Enforcement Results	2
49.	Oviedo Clinton and Valerie Brekke Exhibit	30
50.	Oviedo Staci Starling Exhibit	17
51.	March 19, 2012 Administrative Subpoena for Walgreens Due Diligence Files	2
52.	Letters from Walgreens Legal Counsel to DPM Susan Langston Outlining Walgreens' Response to DEA Due Diligence Subpoena	6
53.	Email: FW: The Two Minute Oxy-Refusal [WAG00000368]	2
54.	Email: re_oxycodone 30 mg [WAG00000460]	2
55.	Email: Re_Please advise on Pain Manag [WAG00000462]	2
56.	Email: Standards of Practice for the Disp [WAG00000464]	2
57.	Email: Re_Handling Pain Management RX [WAG00000660]	2

58.	Email: 0969_001a [WAG00000742]	22
59.	Email: 0969_001a [WAG00000742]	22
60.	Email: Fw_DEA issue at 6094 with attachment [WAG00000813]****	8
61.	Email: _ Oxycodone sales with attachment [WAG00000829]	12
62.	Email: District Notes and Focus Points [WAG00000845]	1
63.	Email: Margate FL Schedule II limitations (Svihra) [WAG00000846]	4
64.	Email: Re: High Quantity Stores 682971 [WAG00000869]	11
65.	Email: Ft Pierce.msg 2 [WAG0000889]	13
66.	Email: Rx Numbers – Oviedo FL (Svihra) [WAG00000902]	2
67.	Email: Oviedo FL (Stahmann) [WAG00000904]	3
68.	Email: Re Fw 682971 - OXYCODONE HCL 30MG TAB [WAG0000908]	11
69.	Email: Fw_3099 Oxycodone Issue [WAG00000919]	2
70.	Email: Re Store #3836 [WAG00000921]	4
71.	Email: Re Fw INC000002834005 Store #3836 WIC#682971 order qty 148 [WAG00000925]	4
72.	Email: 1412 - CII Dispensing Action Plan [WAG00000929]	1
73.	Email: 3525 - CII Dispensing Action Plan [WAG00000930]	1
74.	Email: Fw_Stores with many adjustments [WAG00000948]	2
75.	Email: STORE 3099 – RxS Due Diligence [WAG00001042]	3
76.	Email: Re Store #06997 [WAG00001057]	2
77.	Email: Re Fw Oxycontin question [WAG00001064]	8
78.	Email: Re Fw CII Order [WAG00001087]	17
79.	Email: Florida Focus on Profit (Svihra) [WAG00001107] ****	7
80.	Email: Store 4706 [WAG00001125]	7
81.	Email: Dist #227 Oxycodone Memo August 2011 [WAG00001212]	2

82.	Email: Store 3099 [WAG00001256]	1
83.	Email: Re_3099 [WAG00001260]	2
84.	Email: 1009_001 [WAG00001326]	40
85.	Email: REQUEST REVIEW Florida Pain Management Visits (Merten) [WAG00001638]	1

**** Government Exhibits 60 and 79 are subject to the ongoing litigation involving Respondent's privilege claims. They are produced here as redacted by Respondent pending a resolution of the privilege issue.

Proposed Supplemental Exhibits:

86. Email: Actions Taken in District 21 about CII Dispensing WAG0001740 – 2 pages
87. Email: New Florida Prescribing Law – 3 pages
88. Email: Focus on Compliance Survey – 6 pages
89. Focus on Compliance Survey Results – Excel Spreadsheet – 48 pages
90. List of items produced in response to Administrative Subpoena – 13 pages

OTHER MATTERS

1. Testimony by VTC:

The Government has moved to exclude the proffered testimony of DEA employees and/or Task Force Officers Amber Baginski, Roberta Goralczyk, William Schwartz and Roger Kernicky, witnesses 19-22 in Respondent's Prehearing Statement. Should the Court deny the Government's motion as to any of these witnesses, we request that they be allowed to testify by VTC. It is the Government's intention to have Oviedo Police Chief Jeffrey Chudnow testify in

person, however, given his position, we request the opportunity to present his testimony by VTC only if some currently unforeseen circumstance requires that he remain in Florida. We similarly request the opportunity to present the testimony of George Corripio by VTC if necessary to accommodate his employment schedule.

2. Notice of Additional Basis For Revocation:

The ISO and Prehearing Statement allege that Respondent violated federal statutes and regulations by failing to implement a system to properly identify and investigate suspicious orders. The failure to conduct adequate due diligence as part of a distributor's obligation to maintain effective controls against diversion is further alleged as conduct that would render Respondent's registration inconsistent with the public interest under 21 U.S.C. § 824(a)(4). Florida law imposes similar requirements on wholesale distributors to conduct due diligence and develop a program to identify suspicious orders and prevent suspicious transactions. Florida Statutes (FS) 499.0121 (15). In particular, a wholesale distributor must assess the reasonableness of orders in excess of 5,000 unit doses of any one controlled substance in any one month. FS 499.0121 (15)(b). The Government hereby notifies Respondent that the same evidence and testimony already disclosed may therefore also demonstrate that Respondent has failed to comply with applicable State law under 21 U.S.C. §§ 823(b)(2) & § 823(e)(2).

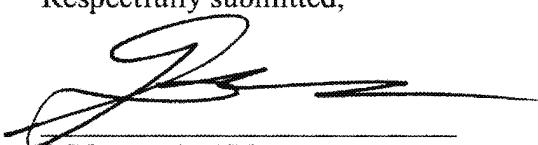
3. Courtroom presence of Government Expert Witness:

The Government requests that its noticed expert, Prof. Paul Doering be permitted to observe all aspects of the hearing in the event he is called in rebuttal.

4. Respondent's Witnesses:

Similar to Respondent's notice at fn 1 of its Prehearing Statement, the Government reserves the right to call any of Respondent's Witnesses on the matters listed in their proposed testimony.

Respectfully submitted,



SCOTT LAWSON
JONATHAN P. NOVAK
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel

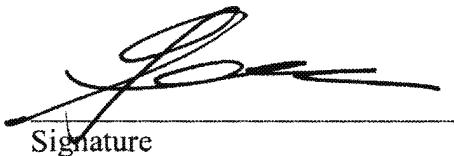
Date: December 7, 2012

CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

Phil Perry
Allen M. Gardner
Nathan H. Seltzer
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004-2232
Fax: 202.637.2201
Email: Phil.Perry@lw.com
Allen.Gardener@lw.com
Nathan.Seltzer@lw.com

12/7/12
Date


Signature

APPENDIX C



www.dea.gov

Springfield, Virginia 22152

NOV 26 2012

IN THE MATTER OF

Walgreen Co.
d/b/a Walgreens # 03629
12028 Majestic Boulevard
Hudson, Florida 34667

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Walgreen Co. d/b/a Walgreens # 03629 ("Walgreens 03629") an opportunity to show cause before the Drug Enforcement Administration ("DEA") at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on March 26, 2013 (if Walgreens 03629 requests such a hearing), or at such time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 03629's DEA Certificate of Registration BW4713992 and deny any pending applications to modify or renew such registration pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4) for reason that the continued registration of Walgreens 03629 is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 03629 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II -V under DEA registration number BW4713992 at 12028 Majestic Boulevard, Hudson, Florida 34667. DEA registration BW4713992 expires by its terms on May 31, 2013.
2. Walgreens 03629 has consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 03629 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a); *see also* Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,315, 62,319 (2012).
3. From late 2010 to November 2011, Walgreens 03629 dispensed oxycodone to customers who presented prescriptions with addresses and locations from 26 states outside of the State of Florida. In addition, Walgreens 03629 dispensed controlled substances, primarily in suspicious

cocktail combinations of oxycodone, alprazolam and carisoprodol, to patients of at least twenty (20) practitioners who were subjected to disciplinary action for dispensing illegitimate prescriptions for controlled substances. Most of these practitioners' registered locations were significant distances from Walgreens 03629. These practitioners include, but are not limited to, the following:

- a. Three hundred fifty four (354) prescriptions for controlled substances prescribed by Ramiro Abaunza, M.D., of Miami, Florida. On November 7, 2011, Dr. Abaunza voluntarily surrendered his DEA registration for cause. Walgreens 03629 is over 300 miles from Miami, Florida.
- b. One-thousand five-hundred fifty (1,550) prescriptions for controlled substances prescribed by Robert R. Reppy, M.D., whose DEA Certificate of Registration was revoked effective November 2, 2011.
- c. Fifty-two (52) prescriptions for controlled substances prescribed by Christopher Wayne, M.D., of Delray Beach, Florida. Dr. Wayne voluntarily surrendered his DEA Certificate of Registration for cause on July 15, 2011, following the emergency suspension of his Florida medical license. Walgreens 03629 is approximately 272 miles from Delray Beach, Florida.
- d. Eight (8) prescriptions for controlled substances prescribed by John T. Legowik, M.D., of Ft. Myers, Florida. Dr. Legowik voluntarily surrendered his DEA Certificate of Registration for cause on November 7, 2011, following the issuance of an Immediate Suspension Order. Dr. Legowik was arrested on April 27, 2012, and charged with illegal distribution of oxycodone and Xanax. Walgreens 03629 is approximately 178 miles from Ft. Myers, Florida.
- e. Eighteen (18) prescriptions for controlled substances prescribed by Randall Wolff, M.D., of Deerfield Beach, Florida. Dr. Wolff's DEA Certificates of Registration were revoked by DEA on February 1, 2011. Walgreens 03629 is approximately 265 miles from Deerfield Beach, Florida.
- f. Three-hundred thirty-five (335) prescriptions for controlled substances prescribed by TJ McNichol, M.D., of Brandon, Florida. Dr. McNichol's DEA Certificate of Registration was revoked by DEA on September 17, 2012. Walgreens 03629 is approximately 57 miles from Brandon, Florida.
- g. Forty (40) prescriptions for controlled substances prescribed by Paul J. Glusman, D.O. of Deerfield Beach, Florida. Dr. Glusman voluntarily surrendered his DEA Certificate of Registration for cause on February 2, 2011, following the issuance of an Immediate Suspension Order. Walgreens 03629 is approximately 265 miles from Deerfield Beach, Florida.

4. On December 21, 2010, a pharmacist employed by Walgreens 03629 notified the Pasco County (Florida) Sheriff's Office to report an individual ("JAM") who attempted to fill a prescription for 270 dosage units of 30mg oxycodone. The prescription, purportedly issued by a Tampa, Florida physician, was later determined to be a forgery. JAM, who at the time of this transaction was a resident of New Port Richey, Florida, abruptly departed from the Walgreens 03629 pharmacy location without filling the forged prescription after learning that pharmacy personnel had contacted local law enforcement. After this incident, Walgreens 03629 filled the following prescriptions for JAM:
 - a. On February 28, 2011, Walgreens 03629 filled a prescription for 150 dosage units of oxycodone 30mg issued to JAM. The prescription was issued to JAM by Ronald Heromin, M.D. (Dr. Heromin), a purported pain management physician practicing in Miami, Florida. JAM paid for the above prescription in cash. JAM's residence in New Port Richey, Florida, is located approximately 304 miles from Miami, Florida, and approximately 308 miles from Walgreens 03629.
 - b. On March 30, 2011, Walgreens 03629 filled prescriptions for 180 dosage units of oxycodone 30mg, 90 dosage units of hydromorphone 8mg (Schedule II controlled substance) and 60 dosage units of alprazolam 2mg issued to JAM by Dr. Heromin. JAM paid for the prescriptions in cash.
 - c. On April 28, 2011, Walgreens 03629 filled prescriptions issued to JAM for 90 dosage units of hydromorphone 8mg and 60 dosage units of alprazolam 2mg. The following day, Walgreens 03629 filled a prescription issued to JAM for 180 dosage units of oxycodone 30mg. These prescriptions were issued by Ramiro Abaunza, M.D. (Dr. Abaunza), a purported pain management physician practicing in Miami, Florida. JAM paid for the above prescriptions in cash.
 - d. On May 27, 2011, Walgreens 03629 filled a prescription issued to JAM for 90 dosage units of hydromorphone 8mg. The following day, Walgreens 03629 filled a prescription issued to JAM for 60 dosage units of alprazolam 2mg. These prescriptions were issued by Dr. Abaunza and JAM paid for the prescriptions in cash.
 - e. On October 11, 2011, Walgreens 03629 filled a prescription issued to JAM for 90 dosage units of diazepam 10mg (Schedule IV controlled substance). On October 13, 2011, Walgreens 03629 filled a prescription issued to JAM for 120 dosage units of oxycodone 30mg. JAM paid for these prescriptions in cash. These prescriptions were issued by Albert Ford, M.D. (Dr. Ford), a purported pain management physician practicing in Tampa, Florida. Walgreens 03629 is approximately 45 miles from Tampa.
5. As noted above, on October 3, 2011, DEA issued a final order revoking Robert R. Reppy, D.O.'s DEA Certificate of Registration. *See Robert Raymond Reppy, D.O., 76 Fed. Reg. 61,154 (2011).*

The effective date of the final order was November 2, 2011. Nevertheless, on November 2, 2011, Dr. Reppy issued a prescription for 220 dosage units of oxycodone 30 mg, which Walgreens 03629 filled on the same day. Walgreens 03629 filled this prescription in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.05.

6. On November 3, 2011, Donald H. Pritchard, M.D. issued a prescription for 60 dosage units of oxycodone 15mg. While the written prescription indicated that it was issued by Dr. Pritchard, the dispensing label affixed to the back of the prescription stated that the prescription was filled by Walgreens 03629 on November 3, 2011, under the [revoked] DEA registration of Dr. Reppy. Walgreens 03629's filling of a Schedule II controlled substance with an improperly affixed prescription label was in violation of 21 C.F.R. § 1306.14(a). *See Rocco's Pharmacy*, 62 Fed. Reg. 3,056, 3,063 (1997).

THE following procedures are available to Walgreens 03629 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03629 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 03629 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show, Walgreens 03629 may file with the DEA a waiver of hearing together with a written statement regarding Walgreens 03629's respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 03629 decline to file a request for a hearing or should Walgreens 03629 request a hearing and then fail to appear at the designated hearing, Walgreens 03629 shall be deemed to have waived the right to a hearing, and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government Counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Robert W. Walker, Counsel for the Government
Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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www.dea.gov

Springfield, Virginia 22152

NOV 26 2012

IN THE MATTER OF

Walgreen Co.
d/b/a Walgreens # 04727
4950 South U.S. Highway 1
Fort Pierce, Florida 34952

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Walgreen Co. d/b/a Walgreens # 04727 ("Walgreens 04727") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on March 12, 2013 (if Walgreens 04727 requests such a hearing), or at such a time designated by the Administrative Law Judge, as to why DEA should not revoke Walgreens 04727's DEA Certificate of Registration BW6561270 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 04727 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW6561270 at 4950 South U.S. Highway 1, Fort Pierce, Florida 34952. DEA Certificate of Registration BW6561270 will expire by its terms on May 31, 2013.
2. Walgreens 04727 consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 04727 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a). *See also* Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Walgreens 04727 dispensed controlled substances when it knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer.
 - a. On September 27, 2010, a Walgreens 04727 pharmacist reported to local law enforcement that he mistakenly provided an extra 120 dosage units of oxycodone (Schedule II) 15mg to a customer. When the pharmacist tried to call the customer to request that he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and viewed the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.
 - b. On November 4, 2010, a Walgreens 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom with the prescription and upon leaving the restroom, left evidence indicating that she had used the oxycodone in an illicit manner. Despite this incident, Walgreens 04727 continued to fill the same customer's oxycodone and alprazolam (Schedule IV) prescriptions on several occasions in November 2010, December 2010 and January 2011.
4. Starting in at least 2010, Walgreens 04727 filled numerous controlled substance prescriptions despite customers exhibiting multiple "red flags" of controlled substance diversion that were never resolved before dispensing. Such "red flags" included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; and individuals paying for prescriptions for controlled substances with cash and non-insurance discount cards. Walgreens 04727's practice of dispensing controlled substances despite unresolved red flags includes but is not limited to the following dispensing events.
 - a. On June 1, 2011, within a 10 minute period, Walgreens 04727 dispensed nearly identical prescriptions for oxycodone 15mg, oxycodone 30mg, and alprazolam 2mg, to five (5) customers, B.A., E.C., N.C., R.O., J.B., all residing at 1205 Seaway Drive, Apartment 4, Fort Piece, Florida. The prescriptions were all issued by Dr. Carrozzella, located in Kissimee, Florida, which is 138 miles away from Walgreens 04727. All prescriptions were paid for with non-insurance discount cards.

- b. On June 28, 2011, Walgreens 04727 dispensed oxycodone 30mg, oxycodone 15mg and alprazolam 2mg to R.O. and N.C. (formerly residing at 1205 Seaway Drive, Apartment 4, Fort Pierce, Florida, newly residing at 1910 Wyoming Avenue, Fort Pierce Florida), E.C. (formerly residing at 1205 Seaway Drive, Apartment 4, newly residing at 9319 Breakers Row, Fort Pierce, Florida), and B.A. (residing at 1205 Seaway Drive, Apartment 4). All prescriptions were issued by Dr. John Carrozzella located in Kissimee, Florida, which is 138 miles away from Walgreens 04727. All prescriptions were paid for with non-insurance discount cards.
- c. On September 21, 2011, Walgreens 04727 dispensed prescriptions for oxycodone 15mg, oxycodone 30mg, and alprazolam 2mg to three (3) customers B.A., E.C., and M.H. All three patients provided new Florida identification cards indicating the same new place of residence: 7500 Pensacola Rd., Fort Pierce, Florida. Walgreens 04727 dispensed the controlled substances despite noting the following red flags on the customers' prescription:
 - i. B.A.: "*uses the same house*" address as E.C. and M.H. Replacement Florida Identification Card was "*replaced same day as pickup???*"
 - ii. E.C.: "*I.D. replaced on today's date?? Strange.*" "*Lives @ same house as [B.A. and M.H.].*"
 - iii. M.H.: Florida Identification Card "*issued same day as oxy pickup?? Strange.*" "*Lives @ same house as [E.C. and B.A.].*"

These prescriptions were all issued by Dr. John Carrozzella located in Kissimee, Florida, and were paid for with non-insurance discount cards. Notably, this dispensing event occurred one month after DEA investigators met with Walgreens representatives regarding the spike in its Florida pharmacies' oxycodone purchases and diversion red flags.

- 5. Walgreens 04727 knew or should have known that the vast increase of customers seeking controlled substance prescriptions created a suspicious situation requiring increased scrutiny, and nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 04727 failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 04727 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, supra; Sun & Lake Pharmacy, Inc. d/b/a The Medicine Shoppe, 76 Fed. Reg. 24,523 (2011); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (2010); Paul H. Volkman, 73 Fed. Reg. 30,630 (2008), pet. for rev. denied, Volkman v. DEA, 567 F.3d 1215 (6th Cir. 2009).*

THE following procedures are available to Walgreens 04727 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04727 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 04727 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04727 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 04727 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges
Michelle F. Gillice, Counsel for the Government
Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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www.dea.gov

Springfield, Virginia 22152

NOV 26 2012

IN THE MATTER OF

Walgreen Co.
d/b/a Walgreens # 06997
785 Lockwood Blvd.
Oviedo, Florida 32765

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Walgreen Co. d/b/a Walgreens # 06997 ("Walgreens 06997") an opportunity to show cause before the Drug Enforcement Administration ("DEA") at the DEA Hearing Facility ("DEAHF") at 1550 Crystal Drive, Suite 901, Arlington, Virginia 22202, or at a location designated by the Administrative Law Judge on March 12, 2013 (if Walgreens 06997 requests such a hearing), or at such time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 06997's DEA Certificate of Registration as a retail pharmacy pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 06997 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW8487438 at 785 Lockwood Boulevard, Oviedo, Florida 32765. DEA registration BW8487438 expires by its terms on May 31, 2013.
2. Since at least 2010, Walgreens 06997 has dispensed controlled substances based on prescriptions issued by physicians who lacked authority to do so, in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.05. These include, but are not limited to, the following circumstances:
 - a. Between December 2010 and July 2011, Walgreens 06997 filled at least two hundred sixty-eight (268) controlled substance prescriptions under an out-of-state registration number for Anthony Wicks, M.D. Dr. Wicks was registered with DEA under

Registration BW7987184 at Visalia, California, until his registration expired on May 31, 2011. Despite the fact that Dr. Wicks was registered out-of-state and that for three months he prescribed controlled substances using an expired registration number, Walgreens 06997 filled his prescriptions, which included more than 27,000 dosage units of 30mg oxycodone (Schedule II) tablets. At least sixty-four (64) of these prescriptions were filled after Dr. Wicks' DEA registration had expired.

- b. On January 20, 2011, DEA registration BL6686541, issued to Ronald Lynch, M.D., was revoked. On June 6, 2011, Walgreens 06997 dispensed 30 dosage units of vyvanse (Schedule II) 30mg tablets as prescribed by Dr. Lynch, despite Dr. Lynch not having a valid DEA registration.
- 3. Walgreens 06997 has consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 06997 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. Such red flags included multiple patients coming with prescriptions for the same drugs in the same quantities coming from the same doctor; patients traveling long distances to the pharmacy; patients with the same address presenting substantially similar prescriptions; and, patients presenting combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam. *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,315, 62,319 (2012).*
- 4. Walgreens 06997 dispensed controlled substances when it knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer.
 - a. Between August 10, 2010, and November 9, 2011, local law enforcement documented seventeen (17) incidents taking place at Walgreens 06997 involving controlled substances, resulting in the arrest of thirty-five (35) individuals for controlled substance-related charges. The Police Chief of the local police department, Jeffrey Chudnow, discussed concerns with Walgreens, both in person and in writing, regarding the association of Walgreens 06997 with these controlled substance incidents. In multiple letters sent to Walgreens 06997, as well as to Walgreens Corporate Headquarters, Chief Chudnow noted controlled substance-related arrests of Walgreens 06997 customers and requested Walgreens' assistance in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.
 - i. By letter dated November 23, 2010, Chief Chudnow advised Walgreens 06997 of the November 11, 2010 arrest of Steven Sean Reynolds for illegal distribution of Xanax (alprazolam, Schedule IV). Reynolds had obtained the Xanax through a

prescription filled by Walgreens 06997, and Chief Chudnow advised the pharmacy that the controlled substance was not used for treatment of injury or illness.

- ii. By letter dated January 19, 2011, Chief Chudnow advised Walgreens 06997 of the January 12, 2011 arrest of Frederick J. Goepel for illegal distribution of oxycodone. The letter stated that Goepel had obtained the oxycodone from Walgreens 06997.
- iii. By letter dated January 21, 2011, Chief Chudnow advised Walgreens 06997 of the January 20, 2011 arrest of Clinton Brekke for possession of oxycodone with intent to sell. The letter stated that Brekke had obtained the oxycodone from Walgreens 06997. Despite notification by law enforcement that Brekke was diverting his oxycodone prescription, Walgreens 06997 again dispensed oxycodone to Brekke on March 13, 2011, April 7, 2011 and April 11, 2011. In addition, the January 21, 2011 letter also identified Valerie Brekke as being involved in the oxycodone-related arrest. Nevertheless, Walgreens 06997 filled prescriptions for Valerie Brekke on March 16, 2011 and April 25, 2011.
- iv. By letter dated January 25, 2011, Chief Chudnow advised Walgreens 06997 of the January 21, 2011 arrest of Matthew S. Miller and Timothy Kemp Dawson for illegal distribution of oxycodone. The letter stated that Miller and Dawson obtained the oxycodone from Walgreens 06997.
- v. By letter dated January 27, 2011, Chief Chudnow advised Walgreens 06997 of the January 26, 2011 arrest of Brian Lee Kemm for illegal distribution of oxycodone. The letter stated that Kemm obtained the oxycodone from Walgreens 06997. The letter further stated that the pills were illegally distributed to Staci Lynn Starling and Anna Marie Girst. Despite the content of the letter, Walgreens 06997 distributed alprazolam, hydromorphone (Schedule II), and oxycodone to Staci Lynn Starling on February 15, 2011, March 14, 2011, and April 13, 2011.
- vi. On February 10, 2011, Chief Chudnow and other representatives of the Oviedo Police Department met with Walgreens Regional Loss Prevention Manager Ed Lanzette in order to discuss his police department's concerns with criminal activities associated with Walgreens 06997. Chief Chudnow provided Walgreens with controlled substance arrest statistics as well as names of practitioners whose names were associated with diversion.
- vii. On November 17, 2011, Walgreens 06997 contacted the Oviedo Police Department to complain about large crowds of people waiting for the pharmacy to open.

- b. Additionally, on February 10, 2011, Chief Chudnow met with Walgreens Loss Prevention officials in an effort to bring further awareness to the problems arising from the Oviedo Walgreens pharmacies and to brief them on the number of drug-related arrests at each of the pharmacies. On March 15, 2011, Chief Chudnow sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo *"has seen the parking lots of your stores become a bastion of illegal drug sales and drug use"* where once the prescriptions are filled, *"the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."*
5. Based on the above, Walgreens 06997 had an abundance of information available, under which it knew or should have known that the vast increase of customers seeking controlled substance prescriptions created a suspicious situation requiring increased scrutiny. Despite the specific guidance provided to Walgreens Corporation by DEA and local law enforcement, and despite the public information readily available regarding the oxycodone epidemic in Florida, Walgreens 06997 nonetheless failed in carrying out its responsibilities as a DEA registrant. Based on the facts as outlined above, Walgreens 06997 has failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). Walgreens 06997 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 06997 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 06997 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 06997 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 06997 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges

Jonathan P. Novak, Counsel for the Government

Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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**U.S. Department of Justice
Drug Enforcement Administration**

www.dea.gov

Springfield, Virginia 22152

FEB 04 2013

IN THE MATTER OF

Walgreen Corporation d/b/a
Walgreens 03836
9332 U.S. Highway 19
Port Richey, Florida 34668

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Walgreens Corporation d/b/a Walgreens #03836 ("Walgreens 03836") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at the DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or at a location designated by the Administrative Law Judge on April 16, 2013 (if Walgreens 03836 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, why DEA should not revoke Walgreens 03836's Certificate of Registration AW8830247, pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because Walgreens 03836's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 03836 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW8830247 at 9332 U.S. Highway 19, Port Richey, Florida 34668. DEA Certificate of Registration AW8830247 will expire by its terms on May 31, 2013.
2. Walgreens 03836 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual

course of their professional practice. Walgreens pharmacists ignored readily identifiable red flags that controlled substances prescribed were being diverted, and they dispensed controlled substances despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a). *See also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Walgreens 03836 pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacists knew or should have known that the controlled substances were abused and/or diverted by the customer.

4. Starting in at least 2010, Walgreens 03836 pharmacists filled numerous controlled substance prescriptions despite customers exhibiting multiple “red flags” of controlled substance diversion that were never resolved before dispensing. Such “red flags” included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; individuals paying for prescriptions for controlled substances with cash and non-insurance discount cards; individuals residing long distances from the pharmacy; and individuals residing long distances from the practitioners from whom the prescriptions were obtained. Walgreens 03836’s practice of dispensing controlled substances despite unresolved red flags includes, but is not limited to, the following dispensing events:

a. From April 2011 through July 2011, Walgreens 03836 pharmacists dispensed oxycodone, alprazolam, and hydrocodone to persons residing in Pensacola, Florida, who had obtained their prescriptions for controlled substances from Ramiro Abaunza, M.D., (“Dr. Abaunza”), a practitioner practicing in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 1397 miles roundtrip. The individuals to whom the controlled substances were dispensed during this time period are J.C., M.S. (April 9, 2011); H.R. (April 15, 2011); H.N. (April 19, 2011); V.J. (April 23, 2011); J.B., M.J., A.J. (April 26, 2011); A.F., D.D., D.S. (April 28, 2011); C.B., Z.S. (May 4, 2011); C.J. (May 5, 2011); C.C., S.C., J.E. (May 7, 2011); J.M., C.T. (May 9, 2011); R.C., C.G., H.P., T.M. (May 11, 2011); A.F. (May 23, 2011); L.J., A.J., C.S. (May 24, 2011); A.J., L.J., P.J. (June 21, 2011); A.J., L.J. (July 18, 2011).

b. On May 5, 2011, a Walgreens 03836 pharmacist dispensed thirty-milligram tablets of oxycodone to C.C. and S.C., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza.

c. On June 21, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to L.J. and P.J., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza.

d. On April 29, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to J.A. and R.E., both of whom lived in Frankfort,

Kentucky, and both of whom obtained their prescriptions from Dr. Abaunza. Additionally, on May 27, 2011, one or more Walgreens 03836 pharmacists dispensed hydrocodone and alprazolam to J.A. and R.E. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2242 miles roundtrip.

e. From April 9, 2011, through May 13, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Decatur, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 9 and May 13 of 2011, a Walgreens 03836 pharmacist dispensed oxycodone to S.M. On April 12, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.M. On April 20, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to F.M. and A.R. On April 23, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to Z.F. On April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to T.H. On May 2, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to M.M. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1760 miles roundtrip.

f. From April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Riceville, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 12 and May 9 of 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.G. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to B.S. On May 26, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to B.S. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1733 miles roundtrip.

g. From April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Athens, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 13, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to K.I. and M.L., who also lived at the same address. On May 11, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to K.I. and M.L. On May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to M.G. On May 9, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to C.H. On May 26, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to M.K. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1750 miles roundtrip.

h. On April 15, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to M.L. and C.P., both of whom resided at the same address in Etowah, Tennessee. The next day, a Walgreens 03836 pharmacist dispensed oxycodone to M.L. and C.P. Both M.L. and C.P. obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida, and obtained the prescriptions for alprazolam and

oxycodone on the same day. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1688 miles roundtrip.

i. On or about April 23, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to G.R., pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. At the time these controlled substances were distributed, G.R. resided in Spring City, Tennessee. In order to obtain these prescriptions and have them filled at Walgreens 03836, G.R. would have had to travel approximately 1762 miles roundtrip.

j. On April 25, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.M., pursuant to a prescription issued by Dr. Abaunza in Miami, Florida. At the time these controlled substances were distributed, J.M. resided in Elora, Tennessee. In order to obtain this prescription and have it filled at Walgreens 03836, J.M. would have had to travel approximately 1829 miles roundtrip.

k. On or about April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to L.S. According to dispensing records provided by Respondent, on or about May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to L.S. and dispensed oxycodone, alprazolam, and hydrocodone to J.S. At the time these controlled substances were distributed, L.S. and J.S. resided in Sweetwater, Tennessee, and obtained their prescriptions from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, L.S. and J.S. would have had to travel approximately 1773 miles roundtrip.

l. On May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to R.D., a resident of Cleveland, Tennessee, pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, R.D. would have had to travel approximately 1665 miles roundtrip.

m. In April 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to R.M., a resident of Cedartown, Georgia. On May 19, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to R.M. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, R.M. would have had to travel approximately 1544 miles roundtrip.

n. On April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and hydrocodone to C.G. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and hydrocodone to J.M. At the time these controlled substances were distributed, both C.G. and J.M. resided at the same address in Lilburn, Georgia, and obtained their prescriptions from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1457 miles roundtrip.

- o. On May 2, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to C.M. and K.S., residents of Columbus, Ohio. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2490 miles roundtrip.
- p. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, and alprazolam to A.N., and oxycodone, hydrocodone, and alprazolam to D.N., both of whom resided at the same address in Hamersville, Ohio. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2390 miles roundtrip.
- q. On April 19, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to D.E., a resident of Dothan, Alabama. On April 26, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to D.E. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, D.E. would have had to travel approximately 1219 miles roundtrip.
- r. On April 21, 2011, a Walgreens 03836 pharmacist dispensed controlled substances, including large quantities of fifteen-milligram tablets of oxycodone and two-milligram tablets of alprazolam, to seven individuals, L.J., C.J., J.W., C.S., D.S., J.I. and C.W., all of whom were residents of the State of Kentucky and two of whom, L.J. and C.J., resided at the same address. Two days later, on April 23, 2011, two Walgreens 03836 pharmacists dispensed controlled substances, including large quantities of thirty-milligram tablets of oxycodone, to the same seven individuals. All of these individuals obtained their prescriptions for the controlled substances from either Charles Kessler, M.D. ("Dr. Kessler"), who was practicing in Plantation, Florida, or Richard Vitalis, D.O. ("Dr. Vitalis"), who was practicing in North Lauderdale, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these seven individuals would have had to travel between approximately 1987 and 2189 miles roundtrip. Moreover, in order to return to Respondent's location on April 23, 2011, and obtain thirty-milligram tablets of oxycodone, these individuals would have had to stay in Port Richey, Florida, for two nights or made a second trip from Kentucky to Respondent's location on April 23, 2011, for which the distance travelled would have been approximately between 1524 and 1724 miles roundtrip. Finally, on April 21 and April 23 of 2011, oxycodone was distributed to L.J. despite dispensing information indicating that L.J. was allergic to opioid analgesics.
- s. On April 14, 2011, Walgreens 03836 pharmacists dispensed large quantities of oxycodone and alprazolam to four individuals, M.C., C.D., K.J., and M.J, all of whom resided at the same address in Kissimmee, Florida. The oxycodone prescriptions for M.C. and C.D. were dispensed by the same pharmacist within five minutes of each other. The oxycodone prescriptions for K.J. and M.J. were dispensed by the same pharmacist

within ten minutes of each other. These individuals obtained their prescriptions for controlled substances from Dr. Vitalis, whose office was located in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 578 miles roundtrip.

t. On April 28 and May 5 of 2011, Walgreens 03836 pharmacists dispensed controlled substances in nearly identical amounts to four individuals, P.W., T.S., J.N., and L.B., all of whom resided at the same address in Kissimmee, Florida. Specifically, on April 28, 2011, the same Walgreens 03836 pharmacist distributed fifteen-milligram tablets of oxycodone to P.W. and J.N. These prescriptions were dispensed within six minutes of each other. On May 5, 2011, the same Walgreens 03836 pharmacist distributed both fifteen and thirty-milligram tablets of oxycodone, and alprazolam to L.B. and T.S. The oxycodone prescriptions were dispensed within eight minutes of each other. All of these prescriptions were obtained from Dr. Vitalis in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 603 miles roundtrip.

u. From April 12 through May 25, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to six individuals, B.M., J.W., B.T., J.G., D.S., and C.S., all of whom resided at the same address in Tampa, Florida, and all of whom obtained their prescriptions from either Dr. Kessler or Dr. Vitalis. Specifically, on April 12, 2011, a Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to J.W. On April 18, 2011, a Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to C.S. On April 21, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to B.T. On April 23, 2011, a Walgreens 03836 pharmacist dispensed a second oxycodone prescription to B.T. On April 27, 2011, the same Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to both D.S. and J.G. The alprazolam prescriptions were dispensed within nine minutes of each other. The oxycodone prescriptions for D.S. and J.G. were dispensed within two minutes of each other. With respect to the oxycodone prescriptions for D.S. and J.G., the controlled substances were packaged in a container bearing an incorrect dispensing date in violation of 21 C.F.R. § 1306.14(a). On May 11, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to J.W. On May 12, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, alprazolam, and carisoprodol to C.S. On May 18, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to B.M. On May 25, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to J.G. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 583 and 587 miles roundtrip.

v. From April 9, 2011, through May 18, 2011, Walgreens 03836 pharmacists dispensed approximately 61 prescriptions for oxycodone, 31 prescriptions for alprazolam, and 7 prescriptions for methadone to persons who obtained their prescriptions from Dr. Kessler and who were residing in the State of Kentucky. Moreover, on May 12, 2011,

one or more Walgreens 03836 pharmacists dispensed oxycodone to five Kentucky residents and two residents of Pensacola, Florida, all of whom obtained their prescriptions from Dr. Kessler. With respect to three of the Kentucky residents who obtained controlled substances from Walgreens 03836 pharmacists on May 12, 2011, C.S., H.J., and T.K, their oxycodone prescriptions were dispensed within a 17 minute period.

w. An analysis of patients who obtained prescriptions for controlled substances from Dr. Kessler and had them filled at Walgreens 03836 shows that, out of 140 different customers, 72% of the customers resided more than 250 miles from Walgreens 03836, 60% resided more than 400 miles from Walgreens 03836, and 51% resided more than 700 miles from Walgreens 03836.

x. From April 8, 2011, through July 20, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, on 55 occasions to persons who obtained their prescriptions from Dr. Ronald Heromin, M.D. ("Dr. Heromin"). At the time these controlled substances were distributed, Dr. Heromin was practicing at offices in Miami and Doral, Florida:

i. Of the 55 prescriptions dispensed, at least 16 prescriptions for Schedule II controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as Fla. Stat. § 893.04(1)(c)(1). At least nine prescriptions for Schedule IV controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.21(a), as well as Fla. Stat. § 893.04(1)(c)(1);

ii. Of the 25 prescriptions which lacked a patient address, eleven prescriptions for oxycodone and five prescriptions for alprazolam were issued to persons residing in Pensacola, Florida, which is approximately 412 miles from Walgreens 03836, and at least 670 miles from either of Dr. Heromin's offices in Doral and Miami, Florida. Moreover, on April 30, 2011, a Walgreens 03836 pharmacist distributed thirty milligram tablets to five individuals who obtained their prescriptions from Dr. Heromin, four of whom were residing in Pensacola, Florida, and one of whom was residing in Wetumka, Alabama. The prescriptions were for quantities of either 180 or 210 tablets each, and all five prescriptions were filled within a 12 minute period by the same pharmacist. In order for the four Pensacola residents to obtain these prescriptions and have them filled at Walgreens 03836, they would have had to travel approximately 1388 miles roundtrip and the patient from Wetumpka, Alabama, would have had to travel approximately 1438 miles roundtrip.

y. From April 25, 2011, through November 5, 2011, one or more Walgreens 03836 pharmacists distributed controlled substances to E.P. and K.P., both of whom resided at the same address in Dothan, Alabama. Specifically, on April 25, 2011, a Walgreens 03836 pharmacist dispensed 60 tablets of Adderall to E.P. On May 25, 2011, a Walgreens 03836 pharmacist dispensed 180-ten milligram tablets of methadone to E.P. On April 27 and August 19 of 2011, a Walgreens 03836 pharmacist dispensed

hydrocodone to K.P., and on October 10 and November 5 of 2011, a Walgreens 03836 pharmacist dispensed Adderall to K.P. On June 22, 2011, the same Walgreens 03836 pharmacist dispensed Adderall and Methadone to E.P. and hydrocodone to K.P. Of the prescriptions described in this paragraph, at least five of them contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as F.S.A. § 893.04(1)(c)(1).

z. From April 9, 2011, through July 19, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, pursuant to 138 different prescriptions issued to individuals residing in Pensacola, Florida. All but three of these prescriptions had been issued by physicians practicing in South Florida, including Drs. Abaunza, Kessler, Vitalis, and Heromin. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 1341 and 1397 miles roundtrip.

aa. From April 9, 2011, through February 28, 2012, Walgreens 03836 pharmacists dispensed approximately 81 prescriptions for controlled substances to individuals residing in Tennessee. The majority (68%) of those prescriptions were issued by physicians practicing in either Doral or Miami, Florida, both of which are more than 270 miles from Walgreens 03836.

bb. From April 9, 2011, through January 28, 2012, Walgreens 03836 pharmacists dispensed approximately 149 prescriptions for controlled substances to individuals residing in Kentucky. Approximately 92% of those prescriptions were issued by physicians practicing in South Florida cities located more than 250 miles from Walgreens 03836.

cc. On April 29, 2011, a Walgreens 03836 pharmacist dispensed 300 four-milligram tablets of hydromorphone to W.W. On May 13, 2011, a Walgreens 03836 pharmacist dispensed hydromorphone to C.W. On June 1, 2011, a Walgreens 03836 pharmacist dispensed 1080 four-milligram tablets of hydromorphone and 300 forty-milligram tablets to oxycodone to C.W. All of the above described controlled substances in this paragraph were dispensed pursuant to prescriptions that contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as FLA. STAT. § 893.04(1)(c)(1). Additionally, the controlled substances provided to C.W. on May 13, 2011, were mislabeled insofar as the container displayed an incorrect dispensing date in violation of 21 C.F.R. § 1306.14(a) and FLA. STAT. § 893.04(1)(e)(2).

dd. In addition to the hydromorphone dispensed to W.W. on April 29, 2011, a Walgreens 03836 pharmacist also dispensed hydromorphone to W.W. on July 27, 2011, and on January 12, 2012. A Walgreens 03836 pharmacist also dispensed hydromorphone to W.W. on January 18, 2010, February 16, 2010, March 16, 2010, April 13, 2010, May 11, 2010, June 9, 2010, July 7, 2010, August 4, 2010, September 29, 2010, October 28, 2010, November 29, 2010, December 28, 2010, January 25, 2011, and February 22, 2011. At the time these controlled substances were dispensed, W.W. resided in Adams,

Kentucky. In order to obtain these prescriptions and have them filled at Walgreens 03836, Respondent's location, W.W. would have had to travel approximately 1814 miles roundtrip.

ee. During January 2011, one or more Walgreens 03836 pharmacists dispensed controlled substances to approximately twenty-two different individuals who presented fraudulent prescriptions that contained no patient address in violation of 21 C.F.R. § 1306.124(a) and FLA. STAT. § 893.04(1)(e)(2). During December 2010, one or more Walgreens 03836 pharmacists dispensed controlled substances to approximately six individuals who presented fraudulent prescriptions that contained no patient address.

ff. Walgreens 03836 pharmacists also filled prescriptions for controlled substances in 2010 and during the first three months of 2011 when they knew or should have known that the prescriptions were not for a legitimate medical purpose and/or were issued outside the usual course of professional practice. This includes, but is not limited to, dispensing oxycodone and alprazolam from December 2010 through February 2011 to customers who resided in Ocala, Florida, and who obtained their prescriptions from Christopher Wayne, D.O., whose offices were located in Ft. Lauderdale and Pembroke Park, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel between more than 650 miles roundtrip.

5. Walgreens 03836 pharmacists knew or should have known that the vast increase of customers seeking controlled substance prescriptions and the large number of customers residing long distances from Walgreens 03836 and/or their respective physicians created a suspicious situation requiring increased scrutiny, and Walgreens 03836 nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 03836 pharmacists failed to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 03836 pharmacists knew, or should have known, that a large number of the prescriptions for controlled substances that they filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, supra; Sun & Lake Pharmacy, Inc., d/b/a The Medicine Shoppe*, 76 Fed. Reg. 24,523 (2011); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149 (2010); *Paul H. Volkman*, 73 Fed. Reg. 30,630 (2008); *pet. for rev. denied, Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).

THE following procedures are available to Walgreens 03836 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03836 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 03836 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03836 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Walgreens 03836 decline to file a request for a hearing or, should Walgreens 03836 request a hearing and then fail to appear at the designated hearing, Walgreens 03836 shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Frank W. Mann, Counsel for the Government

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**U.S. Department of Justice
Drug Enforcement Administration**

www.dea.gov

Springfield, Virginia 22152

FEB 11 2013

IN THE MATTER OF

Walgreen Co.
d/b/a Walgreens # 04391
2501 Virginia Avenue
Fort Pierce, Florida 34981

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Walgreen Co. d/b/a Walgreens # 04391 ("Walgreens 04391") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on April 23, 2013, (if Walgreens 04391 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 04391's DEA Certificate of Registration BW5872494 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 04391 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW5872494 at 2501 Virginia Avenue, Fort Pierce, Florida 34981. DEA Certificate of Registration BW5872494 will expire by its terms on May 31, 2013.
2. Walgreens 04391 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their

professional practice. Walgreens pharmacists ignored readily identifiable “red flags” that controlled substances were being diverted and/or abused, and they dispensed controlled substances despite unresolved “red flags”. *See* 21 C.F.R. § 1306.04(a). *See also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Between January 1, 2010 and April 4, 2012, Walgreens 04391 pharmacists filled numerous prescriptions for controlled substances despite “red flags” indicating a risk of controlled substance diversion and/or abuse. Such “red flags” included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same practitioner; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and benzodiazepines; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; individuals presenting prescriptions for controlled substances issued by multiple practitioners, or “doctor shoppers”; and warnings documented by pharmacy employees regarding physicians prescribing illegitimately. Walgreens 04391’s practice of dispensing controlled substances despite unresolved “red flags” includes, but is not limited to the following incidents:
 - a. Between July 6, 2010 and March 22, 2012, Walgreens 04391 pharmacists filled at least forty prescriptions for hydrocodone, oxycodone 30 mg, oxycodone 60 mg, and oxycodone 80 mg for customer A.R., who obtained these prescriptions from ten different physicians, seven of whom were located in Miami, Florida, approximately 144 miles away from Walgreens 04391. At least four of the above-referenced oxycodone prescriptions were issued by Dr. Armando Falcon and were dispensed to A.R. on November 7, 2011, November, 30, 2011, January 20, 2012, and February 28, 2012, despite the following warning printed on the prescription label beneath Dr. Falcon’s name and recorded in the pharmacy’s electronic dispensing log: “FAKE CII DO NOT FILL CANDY DR.”
 - b. On February 3, 2012 and February 11, 2012, Walgreens 04391 pharmacists filled two prescriptions for oxycodone issued by Dr. Dustin Lee despite the following warning printed on the prescription label beneath Dr. Lee’s name and recorded in the pharmacy’s electronic dispensing log: “FAKE CII DO NOT FILL CANDY DR***FAKE.”
 - c. Between February 28, 2011 and February 3, 2012, Walgreens 04391 pharmacists filled at least twenty-eight prescriptions for oxycodone and Schedule IV benzodiazepines for customer E.O., who obtained the prescriptions from four different physicians, three of whom were located in Miami, Florida, approximately 140 miles away from the pharmacy. On January 4, 2012 and February 3, 2012, Walgreens 04391

dispensed oxycodone to E.O. despite the following warning printed on the prescription label underneath Dr. John Wolf's name and recorded in the pharmacy's electronic dispensing log: "DO NOT FILL ANY FILL ANY CII."

- d. On January 19, 2011, a Walgreens 04391 pharmacist(s) filled eleven prescriptions for oxycodone and alprazolam cocktails to five different customers, all prescribed by Dr. Ralph Miniet, who is located in Fort Lauderdale, Florida, approximately 100 miles away from the pharmacy. According to the time stamp on the prescription labels, all six of the oxycodone prescriptions were dispensed within a ten minute time period.
- e. On November 23, 2010, Walgreens 04391 dispensed 383 dosage units of oxycodone 30 mg and 63 dosage units of alprazolam 2 mg to customer S.W. prescribed by John Davison, M.D. On November 24, 2010, Walgreens 04391 dispensed 483 dosage units of oxycodone 15 mg and 100 dosage units of oxycodone 30 mg prescribed by Dr. Davison. On December 14, 2010, Walgreens 04391 dispensed oxycodone and alprazolam to S.W. *ten days early* pursuant to prescriptions from Leonard Harman, D.O. More specifically, Walgreens 04391 dispensed to S.W. the following controlled substances pursuant to seven prescriptions from Dr. Harman: 210 dosage units of oxycodone 30 mg, 210 dosage units of oxycodone 30 mg; 210 dosage units of oxycodone 15 mg, 210 dosage units of oxycodone 15 mg; 84 dosage units of methadone 10 mg; 84 dosage units of methadone 10 mg; and 63 dosage units of alprazolam 2 mg.

THE following procedures are available to Walgreens 04391 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04391 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 04391 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04391 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 04391 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. See 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges
Michelle F. Gillice, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

**DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152**

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]**
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]**
- (C) [State briefly the position of the person with regard to the particular objections or issues.]**
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]**

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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**U.S. Department of Justice
Drug Enforcement Administration**

www.dea.gov

Springfield, Virginia 22152

FEB 19 2013

IN THE MATTER OF

Walgreen Co.
d/b/a Walgreens # 03099
1525 Colonial Boulevard
Fort Myers, Florida 33907

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Walgreen Co. d/b/a Walgreens # 03099 ("Walgreens 03099"), an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at the DEA Hearing Facility ("DEAHF") 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge, on April 23, 2013 (if Walgreens 03099 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, as to why DEA should not revoke Walgreens 03099's DEA Certificate of Registration AW1366877 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 03099 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW1366877 at 1525 Colonial Boulevard, Fort Myers, Florida 33907. DEA registration AW1366877 expires by its terms on May 31, 2013.
2. Walgreens 03099 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 03099 pharmacists ignored readily identifiable red flags that controlled substances prescribed were being

diverted, and they dispensed despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a). *See also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Walgreens 03099 pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacists knew or should have known that the controlled substances were abused and/or diverted by the customer.
 - a. On September 27, 2010, Fort Myers police received a 911 call from Walgreens 03099 regarding a customer, whose identity was known to Walgreens 03099, who appeared to be under the influence of drugs and was trying to buy syringes. A trespass warning was issued to the customer. Despite this incident, Walgreens 03099 pharmacists filled oxycodone, morphine and alprazolam prescriptions for this customer on numerous occasions between February 3, 2011 and October 10, 2011.
 - b. On September 28, 2010, Fort Myers police documented that a Walgreens 03099 customer, whose identity was known to Walgreens 03099, engaged in a drug deal on the premises of Walgreens 03099 by selling for money controlled substances he had just purchased from Walgreens 03099. The customer had just filled prescriptions for oxycodone and alprazolam that he paid for using cash and with a Walgreens discount card. Nevertheless, Walgreens 03099 pharmacists filled oxycodone and alprazolam prescriptions for this customer on numerous occasions between September 28, 2010 and June 13, 2011.
4. Since at least 2010, Walgreens 03099 pharmacists filled numerous controlled substance prescriptions despite customers exhibiting multiple “red flags” of controlled substance diversion that were not resolved before dispensing. Such “red flags” included: multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone, alprazolam and carisoprodol; individuals from out-of-state or who had travelled significant distances within state to fill prescriptions at Walgreens 03099; and filling new oxycodone prescriptions for customers when fewer than 30 days had elapsed since the customer had filled their previous prescription for a 30-day supply of oxycodone. Walgreens 03099’s practice of dispensing controlled substances despite unresolved red flags includes, but is not limited to, the following dispensing events:
 - a. From January 5, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately forty-two prescriptions for oxycodone 15 mg and 30 mg, alprazolam 2 mg, carisoprodol 350 mg, morphine sulfate 30 mg and 60 mg and zolpidem 10 mg for customer JVL. JVL was ages 35 and 36 during the period of these dispensings. From December 20, 2010 through October 24, 2011,

Walgreens 03099 pharmacists filled approximately thirty-four prescriptions for oxycodone 15 mg and 30 mg, alprazolam 2 mg, carisoprodol 350 mg, morphine sulfate 30 mg and diazepam 5 mg and 10 mg for customer LVL. LVL was ages 33 and 34 during the period of these dispensings. JVL and LVL both resided at the same address in Fort Myers, Florida and both received their prescriptions from the same physician, Emiliya Hill, M.D.

- b. From August 8, 2011 through October 31, 2011, Walgreens 03099 pharmacists filled approximately twelve prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 10 mg for customer GG. GG was age 44 during the period of these dispensings. From August 13, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately nine prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 10 mg for customer RT. RT was ages 43 and 44 during the period of these dispensings. From August 13, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately eight prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 5 mg for customer TT. TT was age 47 during the period of these dispensings. GG, RT and TT all resided at the same address in Fort Myers, Florida and all received their prescriptions from the same physician, Emiliya Hill, M.D.
- c. On April 12, 2011, a Walgreens 03099 pharmacist filled a prescription for 120 dosage units of oxycodone 15 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on April 11, 2011. On April 15, 2011, a Walgreens 03099 pharmacist filled a prescription for 210 dosage units of oxycodone 30 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on April 11, 2011. Walgreens 03099 pharmacists also filled alprazolam and carisoprodol prescriptions for customer CA in April 2011. On May 9, 2011, a Walgreens 03099 pharmacist again filled a prescription for 120 dosage units of oxycodone 15 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on May 9, 2011. On May 12, 2011, a Walgreens 03099 pharmacist again filled a prescription for 210 dosage units of oxycodone 30 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on May 9, 2011. Walgreens 03099 pharmacists also filled alprazolam and carisoprodol prescriptions for customer CA in May 2011.
- d. On May 12, June 9, July 5, July 25, August 22 and October 17, 2011, Walgreens 03099 pharmacists filled prescriptions for 230 dosage units of oxycodone 30 mg for customer MS pursuant to prescriptions written by Emiliya Hill, M.D. In addition to the early dispensings of several of these prescriptions before MS's previous prescriptions had run their course, Walgreens 03099 pharmacists also dispensed alprazolam and carisoprodol to customer MS.
- e. On December 19, 2010, and January 14, February 11, March 11, April 7, May 5, June 2, June 30, July 28, and August 24, 2011, Walgreens 03099 pharmacists filled prescriptions for 90 dosage units of oxycodone 15 mg for customer KW.

All of these prescriptions were written by Emiliya Hill, M.D., except for the April 7 prescription which was written by Natalya Verbinskaya, M.D. On December 18, 2010, and January 15, 2011, Walgreens 03099 pharmacists filled prescriptions for 42 dosage units of alprazolam 2 mg for customer KW pursuant to prescriptions written by Emiliya Hill, M.D. On February 11, March 11, April 7, May 5, June 2, June 30, July 28, and August 24, 2011, Walgreens 03099 pharmacists filled prescriptions for 56 dosage units of alprazolam 2 mg for customer KW. All of these prescriptions were written by Emiliya Hill, M.D., except for the April 7 prescription which was written by Natalya Verbinskaya, M.D.

- f. From December 2010 through October 2011, Walgreens 03099 pharmacists filled identical, or nearly identical, prescriptions for oxycodone for three family members, YH, VH and DH. YH and VH sometimes filled their prescriptions at Walgreens 03099 on the same day. These prescriptions were issued by three physicians who practiced at Southwest Medical Solutions, a pain clinic in Bonita Springs, Florida. The physicians are Lawrence Giventer, M.D. (an ophthalmologist), Connie C. Lee, M.D. and Anthony Posca, M.D. YH was ages 45 and 46 at the time of the dispensings. VH was age 28 at the time of the dispensings and DH was age 24 at the time of the dispensings. Some examples of these dispensings are:
 - i. On July 14, August 11 and October 11, 2011, Walgreens 03099 pharmacists filled identical prescriptions for 120 dosage units of oxycodone 30 mg and 60 dosage units of oxycodone 15 mg that were issued to YH and VH by Dr. Posca.
 - ii. On September 12, 2011, Walgreens 03099 pharmacists filled oxycodone prescriptions that were issued to YH and VH by Dr. Lee. YH's prescription was for 150 dosage units of oxycodone 30 mg and VH's prescription was for 140 dosage units of oxycodone 30 mg.
 - iii. On August 23, 2011, Walgreens 03099 pharmacists filled prescriptions for 120 dosage units of oxycodone 30 mg and 75 dosage units of oxycodone 15 mg that were issued to DH by Dr. Lee. On September 22, 2011, a Walgreens 03099 pharmacist filled a prescription for 150 dosage units of oxycodone 30 mg that was issued to DH by Dr. Posca. On September 24, 2011, a Walgreens pharmacist filled a prescription for 60 dosage units of oxycodone 15 mg that was issued to DH by Dr. Posca.
- 5. Beginning in 2010, the number of customers seeking to fill controlled substance prescriptions and the number of controlled substance prescriptions filled at Walgreens 03099 increased sharply. Walgreens 03099 pharmacists knew or should have known that this vast increase created a suspicious situation requiring increased scrutiny, and Walgreens 03099 nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 03099 pharmacists failed to exercise their

corresponding responsibility regarding the proper dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 03099 pharmacists knew or should have known that a large number of the prescriptions for controlled substances they filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. *See Holiday CVS, L.L.C. d/b/a CVS Pharmacy Nos. 219 and 5195, supra; Sun & Lake Pharmacy, Inc. d/b/a The Medicine Shoppe, 76 Fed. Reg. 24,523 (2011); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (2010); Paul H. Volkman, 73 Fed. Reg. 30,630 (2008), pet. for rev. denied, Volkman v. DEA, 567 F.3d 1215 (6th Cir. 2009).*

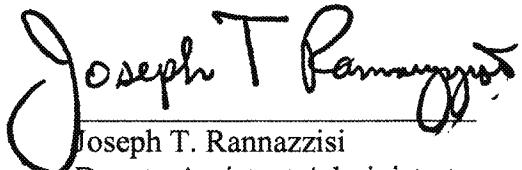
6. On October 30, 2012, pursuant to a Notice of Inspection, DEA Diversion Investigators conducted an inspection of Walgreens 03099 and found the following recordkeeping violations:
 - a. Prescriptions lacking annotations that they were filled by Walgreens' central fill pharmacy, in violation of 21 C.F.R. § 1306.27(a);
 - b. Prescriptions that were not readily retrievable and lacking the red "C" which is required when storing controlled substance prescriptions with non-controlled prescriptions, in violation of 21 C.F.R. § 1304.04(h)(4); and
 - c. Prescriptions lacking the DEA registration number of the prescriber and the address of the patient, in violation of 21 C.F.R. §§ 1306.21(a), 1306.05(a) and 1306.27(a)(2).

THE following procedures are available to Walgreens 03099 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03099 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 03099 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03099 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 03099 decline to file a request for a hearing or should it request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are

deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges
Paul E. Soeffing, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matters of

Walgreen Co.
d/b/a Walgreens #03629

Docket No. 13-9

Walgreen Co.
d/b/a Walgreens #04727

Docket No. 13-10

Docket No. 13-11

Walgreen Co.
d/b/a Walgreens #06997

**PREHEARING STATEMENT ON BEHALF OF
THE GOVERNMENT**

Drug Enforcement Administration
Office of Chief Counsel
8701 Morrissette, Drive
Springfield, Virginia 22152
(202) 307-8010 (office)
(202) 307-4946 (facsimile)
Email: Robert.Walker@usdoj.gov

Dated: January 9, 2013

Pursuant to the Order of the Administrative Law Judge dated December 31, 2012, the United States Department of Justice, Drug Enforcement Administration (DEA), by and through the undersigned attorney, respectfully submits the following pre-hearing statement:

I. ISSUE

Whether the record as a whole establishes that the continued registration of Walgreen Company, d/b/a Walgreens #03629 (Walgreens #03629), as a retail pharmacy under 21 U.S.C. §§ 824(a)(4) and 823(f), would be inconsistent with the public interest.

II. REQUESTED RELIEF

The Government requests: (a) an expedited hearing at a time and place convenient to the respective parties; and (b) a recommended ruling by the Administrative Law Judge favorable to the Government's contention that the DEA Certificate of Registration of the Walgreens #03629 should be revoked and any pending application for renewal or modification of such registration be denied.

III. PROPOSED STIPULATIONS OF FACT

1. Walgreens #03629 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II -V under DEA registration number BW4713992 at 12028 Majestic Boulevard, Hudson, Florida 34667. DEA registration BW4713992 expires by its terms on May 31, 2013.

2. The driving distance between Miami and Hudson, Florida is approximately 307 miles or a more than five hour drive.¹

¹All driving times are approximated by a driving speed of 65 miles per hour.

3. The driving distance between Delray Beach and Hudson, Florida is approximately 272 miles or a four hour and 10 minute drive.

4. The driving distance between Fort Myers and Hudson, Florida is approximately 155 miles or a nearly three hour drive.

5. The driving distance between Deerfield Beach and Hudson, Florida is approximately 274 miles or a more than four hour drive.

6. The driving distance between Fort Lauderdale and Hudson, Florida is approximately 292 miles or a nearly five hour drive.

7. The driving distance between Brandon and Hudson, Florida is approximately 57 miles or a one hour drive.

8. The driving distance between Tampa and Hudson, Florida is approximately 45 miles.

9. Hydromorphone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(12).

10. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(13).

11. Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).

12. Diazepam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(14).

13. Soma is a brand name for carisoprodol, a drug typically used legitimately as a muscle relaxant. While carisoprodol was not a controlled drug prior to January 2012, it has nevertheless been a highly abused pharmaceutical agent, particularly when used in

combination with certain narcotic and benzodiazepine drugs. Effective January 11, 2012, carisoprodol was placed in Schedule IV as a controlled substance pursuant to 21 C.F.R. § 1308.14.

IV. PROPOSED WITNESSES²

1. Susan Langston
Diversion Group Supervisor
Drug Enforcement Administration
Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
2. Gayle Lane
Diversion Group Supervisor
Drug Enforcement Administration
Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326
3. Janet E. Pascall
Task Force Officer
Drug Enforcement Administration
Tampa District Office
4950 West Kennedy Blvd.
Suite 400
Tampa, Florida 33609
4. Donna G. Richards
Diversion Investigator
Drug Enforcement Administration
Fort Lauderdale District Office
1475 West Cypress Creek Road, Suite 301
Fort Lauderdale, Florida 33309
5. Peter Flagg
Diversion Investigator
Drug Enforcement Administration
Tampa District Office
4950 West Kennedy Blvd.
Suite 400
Tampa, Florida 33609

² The Government reserves the opportunity to call any person listed as a witness on behalf of Walgreens #03629.

6. Caren Cohalla
Pharmacist
Walgreens Corporation
Walgreens Company
d/b/a Walgreens #03629
12028 Majestic Boulevard
Hudson, Florida 34667
7. Stuart Eakins
Pharmacy Manager
Walgreens Corporation
Walgreens Company
d/b/a Walgreens #03629
12028 Majestic Boulevard
Hudson, Florida 34667
8. Patricia Gibson
Pharmacy Manager
Walgreens Corporation
Walgreens Company
d/b/a Walgreens #03629
12028 Majestic Boulevard
Hudson, Florida 34667
9. Mary E. Chmielewski Ph.D.
Senior Personnel Psychologist
Research & Analysis (HRN), Human Resources Division
Drug Enforcement Administration
600 Army-Navy Drive, W-3114-4
Arlington, Virginia 22202
10. Paul L. Doering
Distinguished Service Professor of Pharmacy Practice, Emeritus
College of Pharmacy
University of Florida
101 South Newell Drive
HPNP Bldg 212
Room # 3307
Gainesville, Florida 32611

IV. SUMMARY OF TESTIMONY

1. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division³

Following testimony regarding her experience and qualifications as DEA Diversion Program Manager Susan Langston (DPM Langston) will testify regarding the diversion of controlled substances in Florida and the proliferation of “pill mills” employing unscrupulous doctors who dispense controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. In response to this ongoing health threat, on August 18, 2011, DPM Susan Langston, GS Gayle Lane and other DEA investigators met with representatives from Walgreens Corporation to discuss oxycodone diversion and abuse issues in Florida. DPM Langston will testify that DEA investigators advised Walgreens about specific red flags for diversion related to patients, specifically, out-of-state patients, questionable Florida identification cards, cocktail prescriptions for oxycodone 15mg, oxycodone 30mg, alprazolam 2mg, and carisoprodol, customers under the age of 45 and customers paying for prescriptions with cash. DPM Langston will testify that Walgreens #03629 was put on notice that there would be a vast increase of customers seeking controlled substance prescriptions, particularly those involving oxycodone, for no legitimate medical purpose.

DPM Langston will testify to DEA findings that Walgreens #03629 has dispensed controlled substances to customers residing in numerous states and commonwealths outside of Florida. She will testify that Walgreens #03629’s dispensing to out of state customers is particularly problematic when one considers information developed by DEA that as a result of long-standing prescription monitoring programs in Kentucky and Ohio,

³In the event DPM Langston is unable to testify, GS Lane will offer the proposed testimony set forth below.

and with the increased difficulty in obtaining controlled substances from licensed physicians in these jurisdictions, many individuals have found creative ways to circumvent state prescription monitoring programs. As a result of the restricted access to controlled substances in their states, many individuals from Ohio, Kentucky and other states have travelled by the carloads to “pain” clinics located Florida to obtain prescriptions for oxycodone, alprazolam, and carisoprodol. This troublesome trend is particularly acute in the Appalachia region where individuals return to the region with drugs dispensed or prescribed by physicians working at Florida clinics. Because of the easy availability of drugs from these cash-only clinics, drug seeking individuals in the Appalachia region have obtained these drugs and abuse or sell them on the streets both to support drug habits and finance later car trips to Florida. The financing of these trips include the costs charged by the clinics for doctor visits and for drugs dispensed by the clinics. DPM Langton will testify that Walgreens #03629 knew or should have known of these trends before dispensing controlled substances to individuals residing outside of the State of Florida.

2. Gayle Lane, Group Supervisor (“GS”), Miami Field Division⁴

Following testimony regarding her experience and qualifications as a Diversion Group Supervisor, GS Lane will testify to the background of the investigation into Walgreens #03629, which stemmed from Walgreens #03629 and other Walgreens pharmacies’ dramatic spike in oxycodone purchases.

GS Lane will testify that on August 19, 2011, DEA met with Walgreens representatives. GS Lane will testify that she and DPM Langston advised Walgreens of

⁴ GS Lane may testify to portions of DPM Langston’s testimony, in lieu of DPM Langston, as outlined above.

customer and physician specific red flags to look for prior to dispensing prescriptions for controlled substances. These red flags identified addressed both patient and physician conduct, including physicians prescribing the same commonly abused controlled substances, utilizing the same diagnosis, not certified in pain management and/or practicing outside their specialty.

GS Lane will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens #03629. Pursuant to the AIW, investigators obtained inventory records, prescriptions for all Schedule II controlled substances, prescription labels for all dispensed Schedule II controlled substances, and an electronic dispensing log for all Schedule II-IV controlled substances dispensed by Walgreens #03629 between January 1, 2010 and April 4, 2012. GS Lane will introduce Walgreens #03629's dispensing log and summary charts which will show that Walgreens #03629 dispensed controlled substances pursuant to prescriptions that presented obvious red flags.

GS Lane will testify that Respondent's dispensing log reveals that it filled prescriptions issued by doctors who routinely prescribed oxycodone and alprazolam "cocktails", who were located significant distances away from the pharmacy, and whose patients paid for their prescriptions with cash.

3. DEA Task Force Officer Janet E. Pascalli's proposed testimony:

Following testimony regarding her experience and qualifications as a DEA Task Force Officer, Janet E. Pascalli (TFO Pascalli) will testify that in her capacity as Detective for the Pasco County Sheriff's Office (PCSO), her office received numerous reports regarding individuals that frequented Respondent to fill prescriptions. Among the reports received by the PCSO were that addicts and "dopers" would frequent Walgreens

#03629 because of the ease with which they could get combination controlled substance prescriptions filled. She will further testify that the PCSO received additional information that Walgreens #03629 became a favorite location with traffickers of prescription drugs and some of these individuals would travel great distances to fill questionable prescriptions, primarily for oxycodone and alprazolam. TFO Pascalli will testify to numerous calls received by local law enforcement from Walgreens #03629 about individuals who attempted to fill phony prescriptions.

TFO Pascalli will testify that on December 21, 2010, the PCSO received a call from Walgreens #03629 pharmacist Caren Cohalla (Ms. Cohalla) regarding an individual who attempted fill a fraudulent oxycodone prescription. The individual, later identified as James A. McCune (Mr. McCune), attempted to pass a prescription for 270 oxycodone 30mg tablets purportedly issued by Steven Mazer, M.D. (Dr. Mazer), a physician practicing at a Tampa pain clinic. According to Ms. Cohalla, the print on the prescription appeared suspicious (blurry) and the address for the prescribing doctor was misspelled. Ms. Cohalla further informed PCSO that there was an alert in Walgreens #03629's system for Dr. Mazer which stated "Verify, our prescription...pad stolen." When Mr. McCune later returned to the store to pick up the prescription, he apparently overheard a pharmacy technician tell Ms. Cohalla to call 911. Mr. McCune then ran out of the pharmacy without attempting to pick up the prescription.

TFO Pascalli will testify that on April 9, 2011, Mr. McCune was arrested and charged with attempt to obtain a controlled substance by fraud relating to his aforementioned attempt to fill a forged prescription at Walgreens #03629. She will testify that Mr. McCune subsequently entered a guilty plea to one count of attempt to

obtain a controlled substance by fraud in the Sixth Judicial District of Pasco/Pinellas and on June 15, 2012, was sentenced to three years of drug offender probation for this offense.

4. Diversion Investigator Donna Richards' Proposed Testimony:

Following testimony of her background and qualifications, DEA Diversion Investigator Donna Richards (Investigator Richards) will testify regarding DEA's investigation of Mr. McCune's attempt at prescription forgery. Investigator Richards will testify that Mr. McCune attempted to fill a prescription for 270 thirty milligram oxycodone tablets at Walgreens #03629. The prescription, purportedly issued by a Tampa, Florida physician, was later determined to be a forgery. Mr. McCune was a resident of New Port Richey, Florida at the time of this transaction.

Investigator Richards will testify despite being put on notice that he was a prescription forger Walgreens #03629 continued filling prescriptions for Mr. McCune through October 2011. All of the prescriptions were for oxycodone, hydromorphone and/or alprazolam, were paid for in cash and issued by physicians located a significant distance from Walgreens #03629. Investigator Richards will testify to specific prescriptions filled by Walgreens #03629 and Mr. McCune's method of payment in obtaining these medications.

5. Diversion Investigator Peter Flagg's Proposed Testimony:

Investigator Flagg will testify that on April 4, 2012, DEA executed an Administrative Inspection Warrant (AIW) at Walgreens #03629. During the execution of the AIW, investigators obtained inventory records, copies of all Schedule II prescriptions, and dispensing records for Schedule II-IV controlled substances dispensed between

January 1, 2010 and April 4, 2012. Investigator Flagg will testify that a review of the records revealed that Walgreens #03629 filled prescriptions that should have raised concerns or red flags to the pharmacists. Specifically, Walgreens #03629 filled prescriptions issued by doctors who routinely prescribed oxycodone, alprazolam and Soma (carisoprodal) cocktails, practiced outside their specialties and located significant distances away from the pharmacy as demonstrated by the following:

- a. From June 5, 2010 through August 11, 2010, Walgreens #03629 filled eight prescriptions for the aforementioned drug cocktail (oxycodone, alprazolam and Soma) issued by John T. Legowik, M.D. (Dr. Legowik) of Fort Myers, Florida. Fort Myers is approximately 178 miles from Walgreens #03629. Following a DEA investigation into his unlawful handling of controlled substances, on November 7, 2011, Dr. Legowick voluntarily surrendered his DEA Certificate of Registration;
- b. From September 3, 2010 through February 5, 2011, Walgreens #03629 filled 40 prescriptions for the aforementioned drug cocktail issued by Paul J. Glusman, D.O. of Deerfield Beach, Florida. Deerfield Beach is approximately 272 miles from Walgreens #03629. Following a DEA investigation into his unlawful handling of controlled substances, on February 11, 2011, Dr. Glusman voluntarily surrendered his DEA Certificate of Registration. On or about September 29, 2011, in the United States District Court, Southern District of Florida, Dr. Glusman entered a plea of guilty to ten counts of felony distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. Dr. Glusman was sentenced to 46-months of incarceration followed by 36-months of supervised probation;
- c. From January 9, 2010 through November 7, 2011, Walgreens #03629 filled 1,550 controlled substance prescriptions issued by Robert R. Reppy, D.O. (Dr. Reppy) of Tampa, Florida. Of that total, the pharmacy filled 1,094 prescriptions for the aforementioned drug cocktail.⁵

⁵ See proposed testimony of Prof. Paul Doering outlined below.

Investigator Flagg will further testify to DEA investigative findings showing that on November 2, 2011, Dr. Reppy issued a prescription for 220 oxycodone 30 mg. tablets to "LF" of Hudson, Florida and the prescription was filled by Walgreens #03629 that same day. Walgreens #03629 unlawfully filled the aforementioned prescription issued by Dr. Reppy when the latter was no longer authorized to issue prescriptions for controlled substances because on October 3, 2011, DEA issued a final order revoking Dr. Reppy's DEA Certificate of Registration and the effective date of the final order was November 2, 2011. See *Robert Raymond Reppy, D.O.*, 76 FR 61154 (2011).

Investigator Flagg will further testify that on November 3, 2011, Donald H. Pritchard, M.D. (Dr. Pritchard) of Crystal River, Florida issued a prescription for 60 oxycodone 15mg tablets to a patient residing in New Port Richey, Florida. The prescription was issued from Dr. Prichard's practice location in Spring Hill, Florida. While the written prescription revealed that it was issued by Dr. Pritchard, the dispensing label affixed to the back of the prescription revealed that it was filled by Walgreens #03629 on November 3, 2011 under the revoked DEA registration of Dr. Reppy. Investigator Flagg will testify that Walgreens #03629's filling of a Schedule II controlled substance with an improperly affixed prescription label was in violation of 21 C.F.R. § 1306.14(a).

Investigator Flagg will testify to his review of Walgreens #03629's purchases of oxycodone from January 1, 2010 through April 4, 2012, and his comparison of the pharmacy's purchases of oxycodone with 14 pharmacies within the same zip code area (zip code 34667). Investigator Flagg will testify that from January 1, 2010 through December 31, 2010, Walgreens #03629 purchased 913,900 dosage units of oxycodone.

During the same time period the other 14 pharmacies purchased a combined total of 3,417,000 dosage units of oxycodone. From January 1, 2011 through December 31, 2011, Walgreens #03629 purchased 2,211,700 dosage units of oxycodone. During the same time period the other 14 pharmacies purchased a combined total of 2,396,020 dosage units of oxycodone.⁶

Investigator Flagg will testify that his further review of dispensing records of Walgreens #03629 revealed that the pharmacy dispensed oxycodone to customers who presented prescriptions with addresses and locations outside the state of Florida. Specifically, Walgreens #03629 dispensed to customers who resided in 26 states and/or commonwealths including the Appalachia regions of Kentucky, Ohio and Tennessee.

⁶ The Government will present expert testimony of Mary E. Chmielewski regarding the above purchases by Walgreens #03629 as well as the oxycodone purchases of 14 area pharmacies in the 34667 zip code from January 2010 through December 2011. Mary E. Chmielewski will further testify that the above oxycodone purchases by Walgreen #03629 as well as the pharmacy's oxycodone purchases in the period of January 2006 through December 2011 were statistically significant.

Investigator Flagg will testify that pursuant to an administrative subpoena served on Walgreen Co. headquarters in 2012, the company produced a dispensing log from its central fill facility, Central Pharmacy Operations (CPO) located in Orlando, Florida. Investigator Flagg will testify that he identified 25 controlled substance prescriptions in Schedule III-IV from CPO's dispensing log that indicated they were filled by Walgreens #03629. Investigator Flagg will testify that for purposes of verifying the above prescriptions, on October 29, 2012, DEA personnel conducted an inspection of Walgreens #03629 and subsequently obtained copies of the 25 selected prescriptions, as well as the pharmacy's CPO Fill Interstore Transfer Claim Form and a copy of the computer screen printout of the "RX View" for each of the 25 prescriptions. Investigator Flagg will testify that his review of prescriptions obtained from Walgreens #03629 revealed numerous violations, including, but not limited to:

- a. None of the selected 25 prescriptions obtained from Walgreens #03629 contained the word "CENTRAL FILL" written on the face of the original as required by 21 C.F.R. § 1306.27(a);
- b. At least seven of the selected prescriptions did not contain the full address of the patient as required by 21 C.F.R. § 1306.05(a). In addition, one of the aforementioned prescriptions did not contain the DEA registration number of the practitioner as required by 21 C.F.R. § 1306.05(a).
- c. Walgreens #03629 filled a prescription for a controlled substance with a name of the practitioner stamped on the prescription in violation of 21 C.F.R. § 1306.05(d) ("...a computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.").

6. Caren Cohalla's proposed testimony:

Caren Cohalla (Ms. Cohalla) will testify to her training and experience as a registered pharmacist and her employment history with Walgreens #03629. Ms. Cohalla will testify that on December 21, 2010, she placed a call to the aforementioned PSCO regarding Mr. McCune's attempt to fill a fraudulent oxycodone prescription. She will